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Initiation of phase 1 study of belinostat in combination with Bortezomib for Relapsed or Refractory Acute Leukemia or Myelodysplastic Syndromes (MDS)

Copenhagen, Denmark – 11 June, 2010 – Topotarget A/S (NASDAQ OMX: TOPO) announced today that the first patient has been dosed in the investigator-sponsored phase 1 dose escalating study with belinostat in combination with bortezomid (Velcade®) for the treatment of Acute Leukemia or Myelodysplastic Syndromes (MDS) patients. The primary study objective is to determine the recommended phase 2 dose for the combination of belinostat and bortezomib. The study is expected to recruit approximately 24 patients.

"We are very happy to be working with Principal Investigators, Drs. Steven Grant and Beata Holkava, at VCU Massey Cancer Center, Richmond, VA on this study designed to improve on existing therapies to treat patients with relapsed or refractory leukemia or MDS".

"There is abundant preclinical data indicating that HDAC inhibitors such as belinostat and proteasome inhibitors such as bortezomib act synergistically to induce cell death in cancer cells", said Dr. Steven Grant, VCU Massey Cancer Center, Richmond, Virginia, USA. *"Even though there are treatments approved for acute leukemia and MDS there is still a significant unmet medical need for new therapeutic strategies as these patients are rarely cured. We are pleased to be collaborating with Dr. Guillermo Garcia-Manero at MD Anderson on this interesting clinical trial."*

"We are pleased that belinostat continues to be investigated in combination with common chemotherapeutic regimens," said Francois Martelet, MD, Chief Executive Officer of Topotarget. *"We believe belinostat has the potential to be an effective treatment in combination with existing chemotherapeutic agents for the treatment of a variety of cancers, including leukemia and MDS."*

More information on this phase 1 study can be found at www.clinicaltrials.gov, identifier NCT01075425.

Today's news does not change Topotarget's full-year financial guidance.

Topotarget A/S

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Background information

About belinostat

Belinostat (PXD 101) is a Class I and II HDAC inhibitor that is being studied in multiple clinical trials as a single agent or in combination with chemotherapeutic agents for the treatment of various hematological and solid cancers. Its anticancer effect is thought to be mediated through multiple mechanisms of action, including the inhibition of cell proliferation, induction of apoptosis (programmed cell death), inhibition of angiogenesis, induction of differentiation, and the resensitization of cells that have overcome drug resistance to anticancer agents such as platinums, taxanes and topoisomerase II inhibitors. Belinostat is the only HDAC inhibitor in clinical development with multiple potential routes of administration, including intravenous administration, continuous intravenous infusion and oral administration.

Belinostat is currently in a registrational trial, under a Special Protocol Assessment (SPA), as a monotherapy for relapsed or refractory Peripheral T-Cell Lymphoma (PTCL), an indication for which it has been granted Orphan Drug and Fast Track designation by the U.S. Food and Drug Administration. The Company currently plans to file a New Drug Application (NDA) in 2011. Belinostat is also under investigation in a randomized phase 2 trial, as a combination therapy with carboplatin and paclitaxel, for cancer of unknown primary (CUP). Additionally, the National Cancer Institute is currently conducting several clinical trials of Belinostat in a variety of hematological and solid tumors, both as monotherapy as well as combination therapy.

About Topotarget

Topotarget (NASDAQ OMX: TOPO) is an international biotech company headquartered in Denmark, dedicated to improve cancer therapies. Topotarget currently focuses, in collaboration with Spectrum Pharmaceuticals, Inc., on the development in pivotal studies of its lead drug candidate, belinostat, which has shown proof-of-concept as monotherapy in treating haematological malignancies and positive results in solid tumours. Belinostat can be used in combination with full doses of chemotherapy, and is currently in a pivotal trial within PTCL (peripheral T-cell lymphoma). Topotarget's key cancer drugs target HDAC, NAD+, mTOR, Fas ligand and topoisomerase II. The company's first marketed product, Savene®/Totect®, was approved by EMEA in 2006 and the FDA in 2007, and is marketed by Topotarget's own sales force in the US. For more information, please refer to www.topotarget.com.

Topotarget Safe Harbour Statement

This announcement may contain forward-looking statements, including statements about our expectations of the progression of our preclinical and clinical pipeline including the timing for commencement and completion of clinical trials and with respect to cash burn guidance. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Topotarget cautions investors that there can be no assurance that actual results or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors, including, but not limited to, the following: The risk that any one or more of the drug development programs of Topotarget will not proceed as planned for technical, scientific or commercial reasons or due to patient enrolment issues or based on new information from non-clinical or clinical studies or from other sources; the success of competing products and technologies; technological uncertainty and product development risks; uncertainty of additional funding; Topotarget's history of incurring losses and the uncertainty of achieving profitability; Topotarget's stage of development as a biopharmaceutical company; government regulation; patent infringement claims against Topotarget's products, processes and technologies; the ability to protect Topotarget's patents and proprietary rights; uncertainties relating to commercialization rights; and product liability exposure; We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, unless required by law.